

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost



Full length article

Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot



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ARTICLE INFO

Keywords: Prosthesis Amputation Biomechanics Rehabilitation Gait Prosthetic foot



ABSTRACT

Background: Individuals with trans-tibial amputation show a greater peak prosthetic ankle power (push- off) when using energy storing and returning (ESAR) prosthetic feet as compared to solid-ankle cushion-heel feet. ESAR feet further contribute to the users' body support and thus limit prosthetic ankle motion. To improve ankle motion, articulating prosthetic feet have been introduced. However, articulating feet may diminish push-off. Research question: Does a novel prosthetic foot, with a serial layout of carbon fibre leaf springs, connected by a multi-centre joint construction, have advantages in kinematics and kinetics over a conventional ESAR prosthetic foot? >

Methods: Eleven individuals with unilateral trans-tibial amputation were fitted with the novel foot (NF) and a conventional ESAR Foot (CF) and underwent 3D gait analysis. As an additional power estimate of the prosthetic ankle, a unified, deformable, segment model approach was applied. Eleven matched individuals without impairments served as a reference.

Results: The NF shows an effective prosthetic ankle range of motion that is closer to a physiologic ankle range of motion, at 31.6° as compared to 15.2° with CF (CF vs. NF p = 0.003/NF vs. Reference p = 0.171) without reducing the maximum prosthetic ankle joint moment. Furthermore, the NF showed a great increase in prosthetic ankle power (NF $2.89 \, \text{W/kg}$ vs. CF $1.48 \, \text{W/kg}$ CF vs. NF p = < 0.001) and a reduction of 19% in the peak knee varus moment and 13% in vertical ground reaction forces on the sound side for NF in comparison to CF. Significance: The NF shows that serial carbon fibre leaf springs, connected by a multi-centre joint construction gives a larger ankle joint range of motion and higher ankle power than a conventional carbon fibre structure alone. Consequently load is taken off the contralateral limb, as measured by the decrease in vertical ground reaction forces and peak knee varus moment.

1. Introduction

The calf muscles, namely, the soleus and gatrocnemius muscles, contribute substantially to forward propulsion during walking [1]. In a person who has had a trans-tibial amputation (PTTA) these muscles no longer cross a biological ankle and are inoperative, causing functional impairments, primarily a reduced push-off (peak prosthetic ankle power) during late stance. This is likely a cause for increased loading on the sound side and for compensations in non-involved joints [2,3]. In order to reduce such effects, many contemporary prosthetic feet are

constructed with carbon fibre leaf springs. These so-called energy storing and returning feet (ESAR) offer an energy return during terminal stance and pre-swing 2–3 times greater than a SACH foot (solid-ankle cushion-heel) [4]. However, the positive power generation in late stance of ESAR feet is still lower than that in unimpaired individuals [5]. This finding is typical for all passive prosthetic feet [6].

In addition to generating power during late stance, the calf muscles also control forward progression of the tibia during the second foot rocker of the roll over and limit dorsiflexion in late stance [7,8]. This tibial progression also occurs in ESAR feet and is essential for loading

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Abbreviations: PTTA, person who has had a trans-tibial amputation; REF, matched unimpaired individuals for reference purposes; ESAR, energy storing and returning; SACH, solid ankle cushion heel; CoP, centre of pressure; CoM, centre of mass; H1-4, hypothesis 1–4; K-Level, Medicare established K levels in 1995, which are also referred to as Medicare Functional Classification Levels; CF, conventional prosthetic foot (i.e., Vari-Flex *); NF, novel prosthetic foot (i.e., Pro-Flex*); AP, anterior posterior; H, height; GRF, ground reaction forces; UD, unified deformable segment; UD Power, unified deformable segment approach estimate prosthetic ankle power; OA, Osteoarthritis; MANCOVA, multivariate analysis of covariance

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the carbon leaf spring. However, Silverman et al. reported that a normal soleus muscle makes a greater contribution to propulsion than a prosthetic foot, while the prosthesis absorbs more energy during stance, reducing the overall body propulsion [9]. De Asha et al. reported a similar effect and a reduction in that "braking effect" when analysing a hydraulic ankle prosthetic foot [10]. Although this hydraulic ankle dissipates more energy during stance and produces a lower power output than similarly stiff ESAR feet, the participants in this study walked at a faster self-selected walking speed and preferred it conventional ESAR foot [10].

These two functional aspects of calf muscles, power generation and control of shank forward progression, are concurring functional requirements for prosthetic feet. The progression of the prosthetic shank depends on the flexibility of the prosthetic foot during 2nd rocker, while the foot lever is enhanced by higher stiffness. Fey et al. and Adamczyk et al. highlight that there is a compromise between a better body support with the help of a stiffer prosthetic foot and extra forward propulsion as the stiffness of the prosthetic foot decreases [11,12]. In theory, this compromise cannot be avoided with passive prosthetic feet [6] and may deteriorate when using a foot with a single carbon leaf spring, which solely defines forefoot stiffness in conventional ESAR feet. A high stiffness might provide body support in late stance, but at the same time will be possibly hindering in earlier gait phases. This assumption match anecdotal, clinical evidence as PTTA have the perception to 'climb over' the prosthetic-limb [10]. Thus, an ideal prosthetic foot design should offer a gait-phase adapted stiffness.

In addition to consequences on the side of the prosthesis, Morgenroth et al. pointed out that a reduced power generation in late stance of the trailing prosthetic limb can result in greater impact force and an increased knee varus moment of the leading sound limb at initial contact. An experimental foot investigated in their study produced significantly reduced loads on the sound side, as compared to conventional ESAR feet [13].

In this context, the Pro-Flex*1 a novel prosthetic seems promising. It provides a serial layout of flexible carbon fibre leaf springs, connected by a multi-centre joint construction, with its main pivot mimicking an anatomical ankle, potentially allowing for adaptive "ankle" joint motion.

In order to determine the potential benefits of the Pro-Flex*1 foot, the aim of this study was to compare these effects to a common ESAR foot, i.e., the Vari-Flex*2 using conventional 3D gait analysis (CGA) and the unified deformable segment model approach (UD Power) [14].

We hypothesised that the novel prosthetic foot (NF) would show:

- 1 a more effective (i.e., closer to normal) prosthetic ankle range of motion (H1),
- 2 no detrimental effect on effective prosthetic ankle joint moment (H2),
- 3 a better (i.e., closer to normal) maximal power generation at push-off (H3),
- 4 reduced (i.e., beneficial) sound side loads (H4),

as compared to the conventional ESAR foot (CF) during self-selected walking speed on a paved floor.

2. Methods

2.1. Participants

Eleven participants, of whom ten were individuals with a unilateral trans-tibial amputation (PTTA) and K Level 3–4 (described, e.g., by Gailey et al. [15]), were included (Table 1). One participant with a

transverse congenital deformity was included as her involved limb resembles a residual limb after a trans-tibial amputation in form and function. Exclusion criteria were residual limb issues such as edema, pressure sores or wounds and the need for walking aids (e.g. crutches, canes, etc.). Subjects were recruited through our institutional in-house prosthetics and orthotics department, and the outpatient clinic of the hospital. All eleven subjects were fitted at the in-house prosthetics and orthotics department. Their current, well-fitting socket was used throughout the study. Furthermore, subjective feedback was collected during data collection by unstructured interviews as reported in the online supplement.

Data were also collected from eleven age- and sex- matched, unimpaired individuals for reference purposes (REF, two women 37.2 \pm 11.4years; 178.9 \pm 8.1 cm; 76.4 \pm 12.2 kg). Written, informed consent was given by all participants prior to data collection. The study was approved by the local institutional ethics committee and conforms to the Helsinki Declaration.

2.2. Prosthetic feet

The conventional foot (CF, Vari-Flex *2) is a typical design originating from the Flex Foot, which was introduced in 1985 [16]. It consists of a J shaped spring and a heel leaf spring which is bolted to the J shaped spring (Fig. 1A CF).

The novel foot (NF, Pro-Flex*1) is a pilot production of a product that became commercially available in 2016. The design comprises a series of several carbon fibre leaf springs. A foot board (bottom blade), a short J-shaped spring (Top Blade), and a flat spring (Middle Blade/Fig. 1A NF). The top and middle blades are connected via a linkage by three pivot points. During walking this mechanism allows for rolling motion around the main pivot, simulating the 2nd foot rocker in normal gait [7,8]. In the CF, forward progression is achieved via flexing the j shaped spring.

2.3. Study design

PTTA were initially fitted with CF by the same certified prosthetist utilising a L.A.S.A.R Posture ^{*3} and following the alignment recommendations of Blumentritt et al. [17]. PTTA were allowed to become familiar with the CF for two weeks before data collection. On the day of data collection, prior to measurements, all PTTA were first fitted with NF and, to become accustomed to it, walked for approximately 30–45 mins or 1.5 km, both indoors and outdoors around the hospital, over mixed terrains, including level ground, uneven ground, slopes with different gradients and stairs. The PTTA were able to rest during this period; however none of the PTTA needed a longer rest during the accommodation period for NF. Afterwards, data for NF were collected. Subsequently, the prosthetic foot was changed back to CF and subjects had a minimum of 15 mins to become re-accustomed to the prosthetic configuration, they had used previously. Finally, the CF gait data were collected.

Prosthetic alignment between NF and CF was intra-individually recreated utilising the L.A.S.A.R Posture*3 as follows; immediately prior to data collection the vertical laser line was tagged on the CF prosthesis. Additionally, while fitted with the CF, a lateral height marking was added on the socket. Then, the CF – including the pylon – was removed by opening two screws at the proximal, female, pyramid adapter, in order to preserve the settings. NF was then attached using a suitable pylon to reproduce the height, marked with the CF attached. Alignment for NF was adjusted, such that the vertical laser line (L.A.S.A.R Posture*3) matched the marking of the CF prosthetic alignment. After gait analysis, NF and pylon were detached from the socket and the CF

¹ Supplier of Pro-Flex[®] prosthetic foot, Össur Corporate, Reykjavik, Iceland

² Supplier of Vari-Flex[®] prosthetic foot, Össur Corporate, Reykjavik, Iceland

 $^{^3}$ Supplier of alignment testing device L.A.S.A.R Posture $^{\circ}$, Otto Bock HealthCare GmbH, Duderstadt, Germany

Table 1Details for PTTA participants.

	Sex	Height [cm]	Mass [kg]	Age [y]	Time since amputation [y]	Cause of amputation	Liner Suspension method	Habitual prosthetic foot
1	male	187	105	48	11	tumour	Synergy Wave ¹ /pin lock	Vari-Flex ¹
2	male	183	73	24.5	8	tumour	Synergy Wave ¹ / pin lock	Vari-Flex XC ¹
3	male	191	89	55.9	32	bone abscess	Synergy Wave ¹ /pin lock	Vari-Flex XC ¹
4	male	178	82	41.1	5	trauma	Seal in X5 ¹ / valve / knee sleeve	Echelon ²
5	male	176	94	35.6	15	trauma	Synergy Wave ¹ / pin lock	Vari-Flex ¹
6	male	187	94.3	43.6	2	tumour	Synergy Wave ¹ / pin lock	Flex-Foot Assure ¹
7	male	183	69	23.7	4	tumour	Seal in X5 ¹ / valve / knee sleeve	Reflex Shock ¹
8	male	168	83	35.9	26	trauma	Synergy Wave ¹ / pin lock	Vari-Flex ¹
9	male	190	95	44.2	4	trauma	Seal in X5 ¹ / valve / knee sleeve	Vari-Flex XC ¹
10	female	163	62.8	48.7	11	Buerger's disease	Seal in ¹ / valve / knee sleeve	Vari-Flex ¹
11	female	172	44.9	15.8	_a _	_a	Seal in ¹ / valve / knee sleeve	Triton ³
	Mean	179.8	81.1	37.9	11.9			
	SD	9.2	17.4	12.3	10.6			

(PTTA = individuals with a trans-tibial amputation; made by 1 = Össur; Reykjavik; Iceland; 2 = Blatchford Group, Basingstoke; United Kingdom; 3 = Otto Bock; Duderstadt; Germany.

a = no amputation was performed in this participant, she was born with a transverse congenital deformity, see participants paragraph for details).

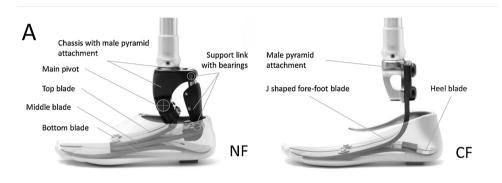
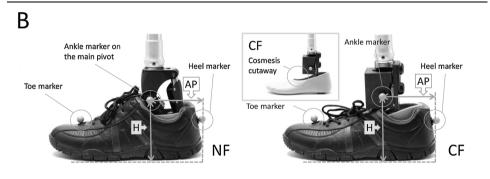


Fig. 1. The two prosthetic feet investigated in this study.

A: NF: Pilot production of a novel foot (NF) (Image shows the now available Pro-Flex*. CF: Conventional energy storing and returning foot (CF, Vari-Flex *2) which served as a reference.

B: NF: Ankle marker was placed on the main pivot of NF (Pro-Flex^{®1}).

CF: Ankle marker anterior-posterior position (AP) and height (H) replicated from NF to CF (Vari-Flex *2).



and original pylon were reattached. Afterwards CF measurements were carried out. This procedure preserved the original alignment of CF and replicated the alignment of CF for NF.

2.4. Data collection, processing, and analysis

Reflective markers were placed on the subjects in accordance with CGA procedures [18,19]. Markers remained in place during NF and CF conditions, except for the ankle markers on the prosthesis. On the prosthetic leg, the ankle markers were placed on the main pivot point for the NF and by using a custom attachment for the CF (Fig. 1B). The attachment offers a flat surface, which was needed, so that placement of the CF ankle marker corresponded to the NF ankle marker location. A laser crosshair was used to reproduce the ankle anterior posterior position (AP) and height (H) of the NF ankle marker position to CF (Fig. 1B). To ensure unrestricted movement of the CF plus the attachment, the CF cosmetic cover was cut out (Fig. 1B, CF). Heel and toe markers were placed on the shoes identically for both prosthetic feet. The prosthetic side knee marker was placed on the lateral

aspect of the socket or on the knee sleeve (if used), estimating the centre of rotation of the knee according to Nietert et al. [20].

For the gait tests, all subjects walked at their preferred walking speed along a 10 m walk-way and wearing the same type of shoes, except for two female PTTA participants who wore their own shoes, as there were no suitable lab owned shoes available. Markers were tracked using a 12 camera motion capture system. Ground reaction forces (GRF) were recorded by two force platforms. Marker trajectories were filtered by utilising the VCM spline filter algorithms. A conventional gait model was applied (Plugin Gait to calculate lower limb joint

⁴ Supplier of laboratory testing shoes, Deichmann, Essen, Germany

 $^{^5}$ Supplier of motion capture system consisting of a Vicon datastation 612 and twelve Vicon MCams, Vicon Motion Systems, Oxford, United Kingdom

⁶ Supplier of force platforms, Kistler Instrumente AG, Winterthur, Switzerland

 $^{^{7}\,\}mathrm{Supplier}$ of VCM spline filter algorithm, Vicon Motion Systems, Oxford, United Kingdom

 $^{^8\,\}mathrm{Supplier}$ of conventional gait model, Plugin Gait, Vicon Motion Systems, Oxford, United Kingdom

 Table 2

 Involved side mean kinematic and kinetic parameters extracted.

	REF (N = 11)				PTTA (N = 11)				
		SD	REF ^a vs. NF ^b P	REF ^a vs. CF ^b p	NF ^b		CF ^b		NF ^b vs. CF ^b
	Mean				Mean	SD	Mean	SD	p
peak dorsiflexion in stance [deg]	13.9	(± 4.09)	0.003	0.008	18.8	(± 4.11)	10.6	(± 1.81)	< 0.000
dorsi plantar flexion ROM [deg]	31.6	(± 4.64)	0.171	< 0.001	27.7	(± 5.17)	15.2	(± 1.86)	0.003
peak dorsi plantar flexion moment [Nm/kg]	1.69	(± 0.15)	< 0.001	< 0.001	1.22	(± 0.22)	1.08	(± 0.22)	0.004
peak dorsi plantar flexion power [W/kg]	4.33	(± 0.62)	0.001	< 0.001	2.89	(± 0.90)	1.48	(± 0.35)	0.003
peak UD power PTTA involved side [W/kg]	3.28	(± 0.53)	0.040	< 0.001	2.77	(± 0.70)	2.12	(± 0.49)	0.006

⁽PTTA = individuals with a trans-tibial amputation; REF = age match reference subjects; NF = novel foot, Pro-Flex*1; CF = conventional foot, Vari-Flex*2.

Table 3Sound side mean kinetic parameters extracted.

	REF (N =	REF (N = 11)			PTTA (N = 11)					
			REF ^a vs. NF ^b	REF ^a vs. CF ^b	NF ^b		CF^b	NF ^b vs. CF ^b		
	Mean	SD	p	p	Mean	SD	Mean	SD	p	
peak external knee varus moment [Nm/kg] peak vertical GRF [N/kg]	0.67 11.65	(± 0.09) (± 0.73)	0.088 0.065	0.699 0.151	0.57 11.03	(± 0.15) (± 1.56)	0.68 12.43	(± 0.19) (± 1.28)	0.010 0.004	

(Peak values extracted from initial contact to mid-stance; PTTA = individuals with a trans tibial amputation; REF = age match reference subjects; NF = novel foot, Pro-Flex*1; CF = conventional foot, Vari-Flex*2.

kinematics and kinetics. In addition, to better estimate prosthetic ankle power, a unified deformable segment approach (UD) [14] was applied and calculated within Visual3D $^{\circ 9}$ software.

The prosthetic segment properties, i.e., in CoM position, were not adjusted for the UD calculations, because we did not measure the moment of inertia for each NF and CF prosthesis in each individual participant.

2.5. Statistics

The mean of at least five trials for each walking condition was used for further analysis. Gait speed, ankle dorsi-plantar flexion range, peak ankle moment, peak ankle power, peak external knee varus moment and peak vertical GRF from initial contact to mid-stance, were extracted using custom Matlab¹⁰ codes, based on the work of Simon et al. [21] and Patikas et al. [22]. Peak UD power was calculated using Visual3D^{*}.9

Normal distribution of all parameters was tested by conducting the Shapiro-Wilk Test. For three parameters (NF ankle dorsi plantar flexion range, CF peak vertical GRF from initial contact to mid-stance, and NF peak ankle power) a non-normal distribution was confirmed. Therefore, we decided to identify any differences with non-parametric statistical tests, a Wilcoxon signed-rank test for related samples (CF vs. PF) and a Mann-Whitney U test for independent samples (REF vs. CF or NF). The level of significance was Bonferroni corrected and set to p < 0.0125 for the involved side parameters and p < 0.025 for the sound side

parameters. All statistical tests were calculated using SPSS Statistics Version ${\bf 24.}^{11}$

3. Results

There was a statistically significant difference of $0.06 \, \text{m/s}$ (p = 0.011) in walking speed between CF ($1.39 \pm 0.17 \, \text{m/s}$) and NF ($1.33 \pm 0.16 \, \text{m/s}$) condition. REF participants walked on average at $1.44 \pm 0.15 \, \text{m/s}$, fairly but not significantly faster than PTTA under both CF and NF conditions (REF vs. NF p = 0.151; REF vs. CF p = 0.401).

NF showed a significant increase of 12.5° in the prosthetic ankle angle range of motion (ROM) and peak dorsiflexion of 18.8° when compared to CF with no significant difference to REF for ROM but with a significantly higher dorsiflexion (Table 2).

The peak external ankle dorsi-flexion moment was significantly smaller than for REF, by 28% in NF and by 36% in CF, with no significant differences in peak external ankle dorsi-flexion moment between prosthetic feet. Similarly, peak positive ankle power was significantly smaller for CF (by 66%) and NF (by 33%) when compared to REF but with NF showing a significantly greater peak ankle power than CF regardless of the model approach (Plugin Gait and UD Model).

The external knee varus moment and the peak vertical GRF for the NF were significantly smaller than for both REF and CF (Table 3).

 $^{^{}a}$ = mean of both limbs in REF N = 22.

 $^{^{\}rm b}~$ =Mean of the involved sides in PTTA N = 11; ROM = range of motion).

^a = mean of both limbs in REF N = 22.

b = Mean of the involved sides in PTTA N = 11; GRF = ground reaction force).

 $^{^{9}}$ Supplier of biomechanical modeling software Visual3D, C-Motion, Inc., Germantown, MD. USA

¹⁰ Supplier of MATLAB software for data analysis, MathWorks, Natick, MA, USA

¹¹ Supplier of statistics software SPSS Statistics Version 24, International Business Machines Corp.(IBM), New York, USA

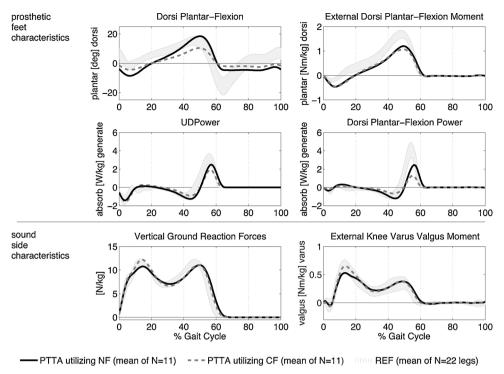


Fig. 2. Average joint kinematics and kinetics of involved and sound side.

4. Discussion

The NF combines two structural aspects: carbon fibre leaf springs, similar to conventional ESAR feet, which are in series and connected by a multi-centre joint system. This structure may provide a compliant prosthetic ankle and PTTA might prefer this system, as reported in several studies [23,24]. In line with this, we could show that the NF indeed has a much more effective prosthetic ankle ROM (hypothesis H1) which did not differ significantly from the anatomic condition. While the CF offers already a greater ROM than, e.g., SACH feet, which is associated with a reduction in sound-side vertical GRF [25,26], the CF foot may still not be satisfactory. Here, it was shown that the CF indeed had a significantly smaller ankle ROM and peak dorsiflexion than REF. Consequently, a larger ankle ROM and peak dorsiflexion would appear to be preferable. Hypothetically, in order to facilitate this in ESAR feet, a more flexible leaf spring could be implemented in CF, but this most likely would work only at the cost of reduced foot leverage, the result being a rather "floppy" prosthetic foot. In their studies Hansen et al. [27] and Fey et al. [28] illustrated the competing features of sufficient ROM and sufficient ankle moment by investigating prosthetic feet of different stiffness. This relationship was further described in the literature as concurring functional requirements for prosthetic feet [11,12]. A too compliant design could even have contrary consequences. In their studies Klodd et al. and Hansen et al. described a "drop off" effect, for prostheses with an excessively flexible forefoot, which led to increased loads on the sound side [24,29]. Consequentially, it is also essential to maintain sufficient leverage and ankle joint moment in prosthetic feet, in addition to providing a good ROM. An effective lever length is vital so that the CoP can progress along the entire length of the foot, as shown by Klodd et al. and Hansen et al. [24,29,30]. Although we cannot draw a conclusion from CoP data, as it is not presented here, it is noteworthy that despite an increased ankle ROM of the NF compared to CF, there was no detrimental effect on prosthetic ankle joint moment (hypothesis H2). Consequentially NF does not seem to suffer from the "drop off" effect, at least when taking prosthetic ankle joint moment into account. All the same it is noteworthy that the increase in ROM for NF is almost entirely due to an

increase in dorsiflexion (Fig. 2, Table 2). Consequentially this could result in a diminished toe support in late stance. This was described by one PTTA (participant no. 3, see online supplement).

The deflection of the leaf springs in the NF foot is directed into a rolling motion around the main pivot (see Fig. 1). Therefore, the mechanical coupling not only controls forward progression of the prosthetic shank, but it also limits this progression via the middle blade moving against the top blade in late stance. As a result, the foot design allows for a stiffness that is adapted to the gait phase. In late stance, this foot does indeed provide larger and closer-to-normal power generation than the CF for push-off, which was formulated as the third hypothesis of this study (H3). Furthermore, we found reduced (i.e. beneficial) loads on the sound side (H4) when using NF, a significant reduction in peak knee varus moment, and vertical GRF when comparing NF to CF. This corroborates findings of Morgenroth et al. [13] and is important since joint loads, in particular the knee adduction or varus moment, have been shown to be related to severity of osteoarthritis (OA) [31,32]. Moreover individuals with a lower limb amputation have an increased risk to develop OA [33-36]. Consequently a reduction of potentially increased sound side loads is per se beneficial, although it cannot be claimed that 19% reduction in external knee varus moment and 13% in vertical ground reaction forces will ultimately reduce the risk of OA in PTTA, as we do not have long term data available. It is noteworthy that our results partly disagree with those of Childers et al. These authors investigated the same prosthetic feet, but could not detect any significant differences in sound-side loads (peak knee varus moment and peak vertical GRF), possibly due to their small cohort (N = 5) and low statistical power, which they cited as a limitation [37]. Furthermore prosthetic alignment was possibly not reproduced as rigorously as in the presented study.

4.1. Limitations

The different accommodation times of two weeks for the CF and only 30–45 min for the re-fitted NF may have affected the results. As NF was a pilot production product we had no experience with the product, decided to have initial trials with the NF in a controlled environment,

and therefore abandoned a two week accommodation. However, we think that a satisfactory accommodation period for NF was given as the participants could accustom to it in various terrains. Another potential limitation of the study was the fixed order of measurements (NF first; CF second). This conceivably may have introduced a bias, but these measurement conditions were chosen due to a number of practical reasons increasing the feasibility of this study, as well as ensuring that removing and replacing markers between experimental conditions was not necessary. PTTA walked slightly, but significantly slower with the NF (0.06 m/s) compared to CF and differences in kinetics may therefore be attributed to speed as a confounding factor [38,39]. Since a violation of normal distribution can occasionally be accepted in parametric tests [40], we retrospectively compared kinetics using a multivariate analysis of covariance (MANCOVA), with speed as a covariate. This retrospective analysis confirmed the results of the original, non-parametric statistical analysis (peak dorsi plantar flexion power conventional model NF 2.89 \pm 0.90, CF 1.48 \pm 0.35 W/kg, p = < 0.001; UD model NF 2.77 \pm 0.70, CF 2.12 \pm 0.49 W/kg, p = 0.002). Therefore we are confident that the differences in kinetics reflect the effects of the feet not the difference in walking speed.

Rusaw and Ramstrand demonstrated that the functional joint centre of ESAR feet is generally lower and more anteriorly located than an anatomic ankle joint and varies between feet [41]. Sawers et al. further showed that the finite helical axis of different prosthetic feet moves considerably during walking [42]. The functional joint centre or finite helical axis of prosthetic feet was not determined in this study. Consequently, for inter-foot consistency, we placed the prosthetic ankle markers at an identical position (see Fig. 1B). Thus ankle motion and the ankle moment were measured at about the same point under both prosthetic foot conditions, allowing us to compare relative motion and moment between NF and CF. Just as in many other such studies, however, absolute values should be interpreted carefully since this may be subject to systematic error [41–43].

4.2. Conclusion

The NF has a potential advantage over the CF as it provides sufficient forefoot leverage and, at the same time, typically offers a much larger ankle ROM. The increase in ROM can be almost entirely lead back to an increase in dorsiflexion. However, this indicates that the trade-off between ankle ROM and ankle power has been solved more beneficially in the NF. This, in turn, takes load off the sound side with possibly beneficial effects regarding early OA. Subjective feedback of the majority of PTTA (see online supplement) is in line with our findings that NF still provides sufficient support, while at the same time offering a perceived smooth roll over. Conversely the increase of peak prosthetic ankle dorsiflexion in NF could have adverse effects. This is evidently a consequence as the action of the triceps surae muscles to plantarflex the ankle is not being delivered by the passive nature and design of the NF. Some users might experience a lack in toe support during late stance. In theory this could be in particular the case for higher walking speeds.

There are no direct supporting data, but given that previous studies have found reduction in the "braking effect" in hydraulically articulating feet, we would speculate that similar effects in NF. I.e. in future studies differences in between NF and CF could be investigated by analysing the forward progression of the centre of pressure trajectory.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.gaitpost.2018.06.022.

References

[1] D.A. Winter, Energy generation and absorption at the ankle and knee during fast,

- natural, and slow cadences, Clin. Orthop. Relat. Res. (1983) 147-154.
- [2] A. Gitter, J.M. Czerniecki, D.M. DeGroot, Biomechanical analysis of the influence of prosthetic feet on below-knee amputee walking, Am. J. Phys. Med. Rehabil. Assoc. Acad. Physiatr. 70 (1991) 142–148.
- [3] D.A. Winter, S.E. Sienko, Biomechanics of below-knee amputee gait, J. Biomech. 21 (1988) 361–367.
- [4] J.M. Czerniecki, A. Gitter, C. Munro, Joint moment and muscle power output characteristics of below knee amputees during running: the influence of energy storing prosthetic feet, J. Biomech. 24 (1991) 63–75.
- [5] A.H. Hansen, D.S. Childress, S.C. Miff, S.A. Gard, K.P. Mesplay, The human ankle during walking: implications for design of biomimetic ankle prostheses, J. Biomech. 37 (2004) 1467–1474.
- [6] H.M. Herr, A.M. Grabowski, Bionic ankle-foot prosthesis normalizes walking gait for persons with leg amputation, Proc. Biol. Sci. R. Soc. 279 (2012) 457–464.
- [7] J. Rose, J.G. Gamble, Human Walking, Lippincott Williams and Wilkins, 2006.
- [8] J. Perry, J.M. Burnfield, Gait Analysis: Normal and Pathological Function, Slack Incorporated, 2010.
- [9] A.K. Silverman, R.R. Neptune, Muscle and prosthesis contributions to amputee walking mechanics: a modeling study, J. Biomech. 45 (2012) 2271–2278.
- [10] A.R. De Asha, R. Munjal, J. Kulkarni, J.G. Buckley, Impact on the biomechanics of overground gait of using an 'Ehelon' hydraulic ankle-foot device in unilateral transtibial and trans-femoral amputees, Clin. Biomech. (Bristol, Avon) 29 (2014) 728-734
- [11] N.P. Fey, G.K. Klute, R.R. Neptune, The influence of energy storage and return foot stiffness on walking mechanics and muscle activity in below-knee amputees, Clin. Biomech. (Bristol, Avon) 26 (2011) 1025–1032.
- [12] P.G. Adamczyk, M. Roland, M.E. Hahn, Sensitivity of biomechanical outcomes to independent variations of hindfoot and forefoot stiffness in foot prostheses, Hum. Mov. Sci. 54 (2017) 154–171.
- [13] D.C. Morgenroth, A.D. Segal, K.E. Zelik, J.M. Czerniecki, G.K. Klute, P.G. Adamczyk, et al., The effect of prosthetic foot push-off on mechanical loading associated with knee osteoarthritis in lower extremity amputees, Gait Posture 34 (2011) 502–507.
- [14] K.Z. Takahashi, T.M. Kepple, S.J. Stanhope, A unified deformable (UD) segment model for quantifying total power of anatomical and prosthetic below-knee structures during stance in gait, J. Biomech. 45 (2012) 2662–2667.
- [15] R.S. Gailey, K.E. Roach, E.B. Applegate, B. Cho, B. Cunniffe, S. Licht, et al., The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate, Arch. Phys. Med. Rehabil. 83 (2002) 613–627.
- [16] V.L. Phillips, Composite Prosthetic Foot and Leg, (1985).
- [17] S. Blumentritt, T. Schmalz, R. Jarasch, Die Bedeutung des statischen Prothesenaufbaus fur das Stehen und Gehen des Unterschenkelamputierten, Der Orthopade 30 (2001) 161–168.
- [18] R.B. Davis, S. Ounpuu, D. Tyburski, J.R. Gage, A gait analysis data collection and reduction technique, Hum. Mov. Sci. 10 (1991) 575–587.
- [19] M.P. Kadaba, H.K. Ramakrishnan, M.E. Wootten, J. Gainey, G. Gorton, G.V. Cochran, Repeatability of kinematic, kinetic, and electromyographic data in normal adult gait, J. Orthop. Res. 7 (1989) 849–860.
- [20] M. Nietert, Unetrsuchung zur Kinematik des menschlichen Kniegelenkes im Hinblick auf die Approximation in der Prothetik, (1975).
- [21] J. Simon, L. Doederlein, A.S. McIntosh, D. Metaxiotis, H.G. Bock, S.I. Wolf, The Heidelberg foot measurement method: development, description and assessment, Gait Posture 23 (2006) 411–424
- [22] D. Patikas, S.I. Wolf, W. Schuster, P. Armbrust, T. Dreher, L. Doderlein, Electromyographic patterns in children with cerebral palsy: do they change after surgery? Gait Posture 26 (2007) 362–371.
- [23] S.U. Raschke, M.S. Orendurff, J.L. Mattie, D.E. Kenyon, O.Y. Jones, D. Moe, et al., Biomechanical characteristics, patient preference and activity level with different prosthetic feet: a randomized double blind trial with laboratory and community testing, J. Biomech. 48 (2015) 146–152.
- [24] E. Klodd, A. Hansen, S. Fatone, M. Edwards, Effects of prosthetic foot forefoot flexibility on gait of unilateral transtibial prosthesis users, J. Rehabil. Res. Dev. 47 (2010) 899–910.
- [25] C.M. Powers, L. Torburn, J. Perry, E. Ayyappa, Influence of prosthetic foot design on sound limb loading in adults with unilateral below-knee amputations, Arch. Phys. Med. Rehabil. 75 (1994) 825–829.
- [26] R.D. Snyder, C.M. Powers, C. Fontaine, J. Perry, The effect of five prosthetic feet on the gait and loading of the sound limb in dysvascular below-knee amputees, J. Rehabil. Res. Dev. 32 (1995) 309–315.
- [27] A.H. Hansen, M.R. Meier, P.H. Sessoms, D.S. Childress, The effects of prosthetic foot roll-over shape arc length on the gait of trans-tibial prosthesis users, Prosthet. Orthot. Int. 30 (2006) 286–299.
- [28] N.P. Fey, The Influence of Prosthetic Foot Design and Walking Speed on Below-Knee Amputee Gait Mechanics, The University of Texas at Austin, 2011.
- [29] A.H. Hansen, D.S. Childress, E.H. Knox, Prosthetic foot roll-over shapes with implications for alignment of trans-tibial prostheses, Prosthet. Orthot. Int. 24 (2000) 205–215
- [30] A.H. Hansen, M. Sam, D.S. Childress, The effective foot length ratio: a potential tool for characterization and evaluation of prosthetic feet, JPO: J. Prosthet. Orthot. 16 (2004) 41–45.
- [31] L. Sharma, D.E. Hurwitz, E.J. Thonar, J.A. Sum, M.E. Lenz, D.D. Dunlop, et al., Knee adduction moment, serum hyaluronan level, and disease severity in medial tibiofemoral osteoarthritis, Arthritis Rheum. 41 (1998) 1233–1240.
- [32] A. Mundermann, C.O. Dyrby, T.P. Andriacchi, Secondary gait changes in patients with medial compartment knee osteoarthritis: increased load at the ankle, knee, and hip during walking, Arthritis Rheum. 52 (2005) 2835–2844.

- [33] D.C. Morgenroth, A.C. Gellhorn, P. Suri, Osteoarthritis in the disabled population: a mechanical perspective, PM & R: J. Injury Funct. Rehabil. 4 (2012) S20–S27.
- [34] R. Gailey, K. Allen, J. Castles, J. Kucharik, M. Roeder, Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use, J. Rehabil. Res. Dev. 45 (2008) 15–29.
- [35] E.D. Lemaire, F.R. Fisher, Osteoarthritis and elderly amputee gait, Arch. Phys. Med. Rehabil. 75 (1994) 1094–1099.
- [36] J. Kulkarni, J. Adams, E. Thomas, A. Silman, Association between amputation, arthritis and osteopenia in British male war veterans with major lower limb amputations, Clin. Rehabil. 12 (1998) 348–353.
- [37] W.L. Childers, K.Z. Takahashi, Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes, Sci. Rep. 8 (2018) 5354.
- [38] M.H. Schwartz, A. Rozumalski, J.P. Trost, The effect of walking speed on the gait of typically developing children, J. Biomech. 41 (2008) 1639–1650.
- [39] C. Kirtley, M.W. Whittle, R.J. Jefferson, Influence of walking speed on gait parameters, J. Biomed. Eng. 7 (1985) 282–288.
- [40] A. Khan, G.D. Rayner, Robustness to non-normality of common tests for the many-sample location problem, J. Appl. Math. Decis. Sci. 7 (2003) 187–206.
- [41] D. Rusaw, N. Ramstrand, Sagittal plane position of the functional joint centre of prosthetic foot/ankle mechanisms, Clin. Biomech. 25 (2010) 713–720.
- [42] A. Sawers, M.E. Hahn, Trajectory of the center of rotation in non-articulated energy storage and return prosthetic feet, J. Biomech. 44 (2011) 1673–1677.
- [43] A.B. Sawers, M.E. Hahn, The potential for error with use of inverse dynamic calculations in gait analysis of individuals with lower limb loss: a review of model selection and assumptions, JPO J. Prosthet. Orthot. 22 (2010) 56–61.